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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/575,245 | 04/13/2007 | Ge Ming Lui | P69492US1 | 6940 |
| 23548 | 7590 | 03/29/2011 | EXAMINER | |
| LEYDIG VOIT & MAYER, LTD 700 THIRTEENTH ST. NW SUITE 300 WASHINGTON, DC 20005-3960 | | | HA, JULIE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 03/29/2011 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCpatent@leydig.com
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| | | |
|------------------------------|--------------------------------------|-------------------------------------|
| Office Action Summary | Application No. 10/575,245 | Applicant(s) LUI, GE MING |
| | Examiner JULIE HA | Art Unit 1654 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34,37-40,43-50 and 52-56 is/are pending in the application.
- 4a) Of the above claim(s) 5-21,24-34,37-40,43-50 and 52-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/26/06,7/20/10</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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DETAILED ACTION

Response to Election/Restriction filed on January 21, 2011 is acknowledged. Claims 1-34, 37-40, 43-50 and 52-56 are pending in this application.

Restriction

1. Applicant's election with traverse of Group 1 and election of species human corneal cells on artificial ECM coated plates in the reply filed on January 21, 2011 is acknowledged. The traversal is on the ground(s) that "the pending application contains several claims that are generic to and, thus, link two or more categories of subject matter...Examiner has not shown that a search and examination of at least, pending claims of Groups I-V, and XIV together would cause a serious burden". This is not found persuasive because the instant application is a 371 of a PCT. In the previous office action, lack of union of invention was established. Therefore, Applicant's arguments are moot.

The requirement is still deemed proper and is therefore made FINAL. Claims 6, 8-21, 24-34, 37-40, 43-50 and 52-56 are hereby withdrawn from further consideration as being drawn to nonelected inventions. A search was conducted on the elected species, and this appears to be free of prior art. The search was extended to other species, and prior art was found. Claims 5 and 7 are withdrawn from further consideration as being drawn to the species found in prior art. Claims 1-4 and 22-23 are examined on the merits in this office action.

TRADEMARK in the SPECIFICATION

2. The use of the trademark NOVOZYM® has been noted in this application at page 6, paragraph [0094], line 10. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Rejection

35 U.S.C. 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 recites the limitation "The method of non-enzymatic harvesting" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1 is an independent claim, thus the recitation of "The method" lacks antecedent basis.

35 U.S.C. 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyata et al (Cornea, 2001, 20(1): 59-63, filed with IDS).

7. Miyata et al teach all of the active method steps of instant claims 1-4. Miyata et al teach that human corneal endothelial cells (HCEC) were obtained from the remaining corneoscleral rims of seven human corneas...Primary cultures were established from explant of the endothelial cell layer, and were propagated on culture dishes coated with bovine corneal endothelial extracellular matrix (see abstract, Methods), meeting the limitation of claims 1-4. The reference teaches growth factors such as fibroblast growth factor, 10% fetal bovine serum, 5% calf serum in Dulbecco modified Eagle medium (see p. 59, Materials and Methods, Media and Culture Conditions). The reference teaches growing the corneal endothelial cells to confluency (see p. 61, Primary Culture of HCEC). Since the reference teaches all of the active method steps of instant claims, the reference anticipates, instant claims 1-4.

8. Claims 1-3 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Engelmann et al (Ophthalmolgy, 1999, 555-562, filed with IDS).

9. Engelmann et al teach in vitro cultivation of human endothelial cells and their transplantation on the Descemet membrane of donor corneas (see p. 556, "Materials and Methods"). The reference teaches in vitro proliferation of human adult corneal cells by the development of defined cell culture conditions, including supplementation of culture medium with specific growth factors and substances, meeting the limitation of

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instant claim 1. The reference teaches isolation and in vitro cultivation of human endothelial cells (see p. 556, "Background"), meeting the limitation of instant claim 2. The reference teaches cells isolated from peripheral part of donor corneas (see p. 556, "Results"), meeting the limitation of instant claim 3. The reference further teaches molecular biological examinations of the endothelial cells and DNA synthesis examination (see p. 556, "Results" and "Conclusion"), meeting the limitations of instant claims 22-23. Therefore, the reference anticipates instant claims 1-3 and 22-23.

10. Claims 1-4 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Amano (Nippon Ganka Gakkai Zasshi, Dec. 2002, 106(12): 805-836, abstract filed with IDS, and used for this rejection).

11. Amano teaches corneal endothelium that is critical for corneal transparency and the reconstruction of cornea utilizing cultured human corneal endothelial cells (HCECs) (see abstract, lines 5-7). The reference teaches culturing HCECs by using culture dishes pre-coated with extracellular matrix produced by calf corneal endothelial cells and culture media that contained basic fibroblast growth factor and fetal bovine serum (see abstract, lines 7-9), meeting the limitation of instant claims 1-4. The reference teaches that telomeres of HCECs were measured as terminal restriction fragments (TRF) by Southern blotting (see abstract, lines 11-12), meeting the limitation of instant claims 23-24. The reference teaches all of the active method steps of instant claims, therefore, the reference anticipates instant claims 1-4 and 23-24.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Primary Examiner, Art Unit 1654